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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,614	10/24/2003	Mark C. Kraus	905.047US1	3446

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/692,614

Applicant(s)

KRAUS ET AL.

Examiner

Christopher D. Koharski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) 1 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>see attached (x3)</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements (IDS) that were submitted on 10/24/2003, 12/22/2003, and 4/8/2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statements.

Claim Objections

Claims 1 and 13 are objected to because of the following informalities: Regarding claim 1, Examiner acknowledges Applicant means to invoke mean plus function 112 6th paragraph and the claim scope will be interpreted as such, Examiner suggests adding the specific structure covering the retracting means to the claim. Regarding claim 13, the disclosed "needle catch" could not be located in Applicant's disclosure and therefore lack support, only the catch (426) that is disclosed to be part of the sheath was found, which is not the needle.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-24 and are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11, 13-21 and 23-30 of U.S. Patent No. 6,641,564. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the current pending application are anticipated by the claims in the cited US patent.

Application claim 1 requires:

1. An introducing apparatus comprising:
 - a tubular sheath extending from a sheath proximal end to a sheath distal end, the sheath sized to receive a dilator therethrough;
 - the dilator extending from a dilator proximal end to a dilator distal end;
 - a needle disposed within the dilator, the needle extending from a needle proximal end to a needle distal end and including an intermediate portion therebetween; at least a portion of the needle is at least as flexible as the dilator;
 - the needle distal end extending out of the dilator distal end in a first position, the needle distal end retracted within the dilator distal end in a second position; and
 - means for retracting the needle distal end within the dilator.

While patent claim 1 requires:

1. An introducing apparatus comprising: an elongate tubular sheath

extending from a sheath proximal end to a sheath distal end, the sheath having a bore including an internal diameter sized to receive a dilator therethrough,

the internal diameter sized to receive medial instruments therethrough; the dilator extending from a dilator proximal end to a dilator distal end;

a needle disposed within the dilator, the needle extending from a needle proximal end to a needle distal end and including an intermediate portion therebetween, the intermediate portion is flexible;

the needle distal end extending out of the dilator distal end in a first position, the needle distal end retracted within the dilator distal end in a second position;

and a needle retraction mechanism coupled with the needle and the dilator, and the needle is retractably coupled with the dilator.

Thus it is apparent that the application claims are broader than the patent claims and the subsequent patented independent and dependant claims 1-11, 13-21 and 23-30 encompass application claims 1-24. Following the rationale in *In Re Goodman* cited in the preceding paragraph, where Applicant has once been granted a patent containing a claim for the specific or narrower invention, Applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting a terminal disclaimer.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 8-9, 12-14 and 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Gould (5,910,133). Gould discloses a transintimal recanalisation device.

Regarding claims 1-4, 6, 8-9, 12-14 and 18-22, Gould discloses an introducing apparatus comprising a tubular sheath (3), a dilator (2), and a needle (1) disposed in the dilator wherein a portion on the needle is as flexible as the sheath (Figure 1) with a means for retracting the needle distal end via locking hub (4,5). The different sections/tubes of the instrument can be separated (Figure 2) using the locking hub assembly and the flexibility of the needle and dilator sheath (col 4, ln 58-67, col 5, ln 22-23, 29-39) can be adjusted using nitinol-based materials. Additionally the hub assembly includes a needle catch (Figure 1) that limits movement of the needle within the assembly. Examiner asserts that the device disclosed performs the method as claimed by Applicant (cols 1-4) in which a needle is disposed within a dilator and is coupled to the distal thereof and placed into the introduction apparatus and the locking hub sections act to retain the respective elements in a specific orientation (Figures 1-2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5, 7 and 24 are rejected under 35 U.S.C 103(a) as being unpatentable over Gould in view of Dysarz (6,235,003). Gould meets the claim limitations as described above except for needle that comprises a flexible coil and catch.

However, Dysarz teaches an spring needle cannula with a latching member.

Regarding claims 5, 7 and 24, Dysarz teaches a needle that comprises a spring coil (11) and catch member (15) that is sized and shaped to limit movement of the needle distal end (Figure 2).

At the time of the invention, it would have been obvious to use the needle assembly of Dysarz with the system of Gould because the flexible needle and catch allows for increased movement and the ability to traverse wide angle vessels and body regions. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Dysarz.

Claim Rejections - 35 USC § 103

Claims 10-11, 16-17 and 23 are rejected under 35 U.S.C 103(a) as being unpatentable over Gould in view of Walker (5,755,693). Gould meets the claim

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limitations as described above except for the sheath comprising a valve member assembly.

However, Walker et al. teaches a bloodless splittable introducer.

Regarding claims 10-11, 16-17 and 23, Walker et al. teaches a valve (30F) coupled the sheath (18) of an introducing assembly that comprises a sliding valve member with a tab (66) that moves between two positions to seal the sheath (Figures 11-12).

At the time of the invention, it would have been obvious to include the valve assembly of Walker et al. to the system of Gould because the addition of the valve assembly allows for reduction of blood loss during treatment and help improve sterility. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Walker et al.

Claim Rejections - 35 USC § 103

Claim 15 is rejected under 35 U.S.C 103(a) as being unpatentable over Gould in view of Russell et al. (5,013,304). Gould meets the claim limitations as described above except for a gas permeable filter located in the blood chamber.

However, Russell et al. teaches an intravascular catheter assembly.

Regarding claim 15, Russell et al. teaches the use of a gas permeable filter (18) in a introducer assembly (Figures 1-2).

At the time of the invention, it would have been obvious to add the filter of Russell et al. to the system of Gould because the filter would allow for pressure

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equalization in the assembly and improve sterility on the system. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Russell et al.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

10/17/2006


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